

REMARKS

Applicants submit this Response in reply to the final Office Action mailed November 24, 2006.

The Office Action has rejected claims 66-94 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of Liljestrand et al. (U.S. Patent No. 6,200,531 B1) in view of Ghaed et al. (U.S. Patent No. 5,466,416 A). The Office Action alleges that Liljestrand teaches an apparatus with many of the same limitations as are presently claimed. The Office Action further argues that Ghaed teaches "the use of a fluid handling system that has a fluid heater system" (Office Action at p. 3), and that Liljestrand teaches "that the electrochemiluminescence process occurs at the working electrode 140 site when testing assay samples." (*Id.*)

An obviousness-type double patenting rejection requires particular consideration, and only limited consideration of the specification is permitted, according to the M.P.E.P. The Applicants previously acknowledged, and acknowledges once again here, that consideration of the specification is permitted for certain limited reasons. Overall, however, an obviousness-type double patenting rejection is analogous to an obviousness rejection based on 35 U.S.C. § 103, except that the patent principally underlying the double patenting rejection is not considered prior art. See M.P.E.P. 804(II)(B)(1). For this reason, as stated directly in the M.P.E.P., an obviousness-type double patenting rejection is only appropriate if the **claimed** subject matter of an application claim is not patentably distinct from the **claimed** subject matter in a commonly owned patent. *Id.* The M.P.E.P., however, makes clear that one can only rely on the specification in an obviousness-type double patenting rejection for very

particular reasons. The specification "can be used as a dictionary to learn the meaning of a term in the patent claim" or "the portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." See M.P.E.P. 804(II)(B)(1) (citations omitted).

The Office Action did not present such an analysis in rejecting claims 66-94 of this application. Indeed, contrary to the guidance of *General Foods*, rather than comparing the application claims to the patent claims for what they define, the Office Action appears to look to the patent claims for what they allegedly teach as though the claims were a prior art reference. Such an analysis is improper under the case law and the M.P.E.P. The Office Action acknowledges that "[t]he MPEP clearly indicates that in an obviousness-type double patenting rejection, the specification of the patent may be used as prior art in determining if the present application claims an obvious variation of an invention claimed in the cited prior patent." (Office Action at p. 6, emphasis added). The disclosure may not be used as a prior art reference.

As also set forth above, M.P.E.P. § 804(II)(B)(1) requires obviousness-type double patenting rejections to make clear "the differences between the inventions defined by the conflicting claims . . . and . . . the reasons why a person of ordinary skill in the art would conclude the invention defined in the claim in issue is an obvious variation of the defined in a claim of the patent." (Emphasis added.) The Office Action has not made clear the differences between the inventions defined by the conflicting claims, nor has the Office Action provided any reasons as to why one of ordinary skill in the art would find those differences to be obvious variants of one another.

The Office Action repeatedly relies on the specification improperly in constructing a double patenting rejection. Indeed, the Office Action stated that "Liljestrand does teach that the electrochemiluminescence process occurs at the working electrode 140 site when testing assay samples (see, e.g., 14, lines 41-64)." (Office Action at p. 3). This portion of the specification reads as follows:

As shown in FIG. 3B, the registration of working electrode 140, opening 137, opening 133, transparent base 127, aperture 125, conductive window 124, optical filter 123 and light detector 122 is an important feature of the invention. Proper registration of these elements ensures optimal transmittance of light from the vicinity of working electrode 140 to light detector 122. Additionally, registration of magnet 146 and opening 145 with working electrode 140 allows for the precise and efficient application of magnetic energy at working electrode 140. Such magnetic energy is used to attract magnetic particles from an assay sample to working electrode 140 where electrochemiluminescence may be induced. Preferably, opening 133 itself functions as an optical element that defines the region of working electrode 140 and ECL chamber 139 from which induced electrochemiluminescence may propagate to light detector 122. Per design, counter electrode 136 may block undesired light generated in certain regions of ECL chamber 139. Preferably, the size and shape of the counter electrode aperture 133 is designed to maximize collection of light emitted from those regions of the working electrode 140 where magnetic beads have been deposited and minimize collection of light emitted from other regions of the working electrode 140.

Liljestrand at col. 14:41-64.

This is impermissible argument, however, because the M.P.E.P. and case law require obviousness-type double patenting rejections to compare only the **claimed** subject matter of an application claim to the **claimed** subject matter in a commonly owned patent, as explained above. The Office Action did not address Applicants'

response to this argument. Because of the Office Action's improper reliance on the specification, however, applicants respectfully request consideration of this argument. The Office Action here attempts to rely on the specification, but does so outside the permissible scope of such reliance as outlined by the M.P.E.P. The specification "can be used as a dictionary to learn the meaning of a term in the patent claim" or "the portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent." See M.P.E.P. 804(II)(B)(1) (citations omitted).

In this case, the relied-upon portion of the specification is not necessary to support the apparatus claims in Liljestrand. The fact that the ECL process occurs at the working electrode is not necessary to construct the claimed apparatus, or understand the scope of the claims. Nothing in the claims of Liljestrand relate to the location of the ECL process, its temperature, or the use of any heaters. As such, this portion of the specification is not required to provide support for the patent claims, nor is it necessary to address an obvious variant of an invention or to act as a dictionary for the meaning of a term in the patent claim. Therefore, the Office Action is attempting to use the specification improperly in constructing this double patenting rejection.

The Office Action continues to rely improperly on the specification. On page 4 of the Office Action, the Office Action relies on Liljestrand at column 17, lines 60 through column 18, line 5 for the teaching of a heater in claims 67, 75, 76, 78, and 85. That portion of the specification reads as follows:

Heater 216, coupled to temperature controller 224, is a conventional controlled heating device for heating input fluid to be introduced into flow cell 120. Temperature controller 224 is a conventional temperature controller for controlling the operation of heater 216 and responding to control signals from main controller 214. Controller 224 receives power from power source 202 via main interface 210 and, preferably, controls the flow of power to heater 216. Controller 224 may include temperature sensors to determine the temperature of input fluids or, alternatively, such sensors may be incorporated into heater 216. Optionally, heater 216 and/or temperature controller 224 may be omitted.

Liljestrand at col. 17:60-col. 18:5.

The claims of Liljestrand, however, never recite a heater. Nothing in the claims of Liljestrand relate to a heater, or the temperature of the reaction. Therefore, this portion of the specification is not required to provide support for the claims, nor it is necessary to address an obvious variation of the invention or to act as a dictionary for the meaning of the term in the patent claim, which are the only permissible considerations of the specification in such an analysis, according to the M.P.E.P. The Office Action, again, improperly relies on the specification relating to the heater, a limitation never recited in the claims of Liljestrand, on page 4 of the Office Action in reference to claim 71. Once more, the Office Action improperly relies on the specification in the same way, in relation to sensors that may be incorporated with the heater, which is a limitation never recited in the claims of Liljestrand. See Office Action at p. 5.

Moreover, the Office Action has not shown that claims 66-94 of the present application are not patently distinct from the claims of the commonly owned patent. For example, claims 66-94 of the present application require a heater thermally coupled to

the working electrode, while the claims of Liljestrand do not. As with the previous argument, the Office Action again did not address applicants' response on this issue. This fact that the pending claims are patentably distinct from the claims of the commonly owned patent is an issue completely independent from the *General Foods* arguments addressed in the current Office Action. It should be given due consideration.

Here, the Office Action appears to rely on Ghaed for the teaching of a heater. (See Office Action at p. 3). Ghaed, however, does not teach the heater disclosed in the present invention. In Ghaed, Figure 10 illustrates the heater block 570 separated from the flow cell 50 by the outlet line 802. (See Ghaed Fig. 10). The present application eliminates this separation, requiring that the heater be thermally coupled to the electrode. See Specification at 29, 31. Therefore, the Office Action has not shown that a person of ordinary skill in the art would not conclude that the methods defined in the claims of the present application are an obvious variant of the device defined in the claims of Liljestrand in view of Ghaed.

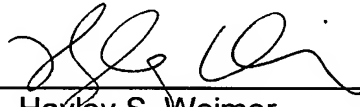
For the above reasons, a *prima facie* case has not been made to support the double patenting rejection. Applicants respectfully submit that the double patenting rejection of claims 66-94 is improper and should be withdrawn.

Please grant any extensions of time required to enter this Response and charge
any required fees not otherwise provided for to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: February 26, 2007

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